REMARKS

Request to Withdraw Finality of Office Action mailed September 8, 2005

The present application came out of a period of suspension on May 9, 2005 when the Examiner issued an Office Action. On July 19, 2005, Applicants filed a paper in the present case to copy claims from U.S. Patent No. 6,764,679, issued July 20, 2004. Applicants expressly stated at two distinct places in their July 19, 2005 submission that the amendments therein were "not intended to constitute a response to the Office Action mailed May 9, 2005" but instead were being filed to ensure that the statutory deadline set by 35 U.S.C. § 135(b)(1) was met. Applicants further indicated that their complete reply under 37 C.F.R. § 1.111 to the Office Action mailed May 9, 2005 was being prepared and would be filed in advance of the 6-month statutory deadline (November 9, 2005). On September 8, 2005, the Examiner issued a Final Office Action in response to Applicants' July 19, 2004 submission.

The present response is intended as Applicants' response to the May 9, 2005 office action. Accordingly, Applicants have paid the two months extension of time that would have been necessary to respond to the May 9, 2005 office action on or before October 11, 2005[1]. As additional rejections were raised in the September 8, 2005 office action, Applicants will also address these rejections herein. However, Applicants respectfully request that the Examiner withdraw the finality of the September 8, 2005 office action, consider the remarks and amendments made herein, and then issue a notice of allowance, a new office action and/or other appropriate paper in the present application.

Status of the claims

Upon entry of this amendment, claims 49-123, 138, 139, 141-145, and 147 will be pending. Claims 124-137, 140 and 146 have been cancelled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of the cancelled claims in one or more divisional or continuing applications.

Claim Objection

In the office action mailed September 8, 2005, the Examiner objected to claim 131 because of a grammatical error and required appropriate correction. Applicants' cancellation

[1] Under 35 U.S.C. § 21, because October 9 and 10 were, respectively, a Sunday and a Federal holiday, it is permissible to file the present response on October 11, 2005 and pay only a two month extension of time.

of claim 131 obviates or overcomes this objection. Accordingly, Applicants respectfully request that this objection be withdrawn.

Claim Rejections under 35 U.S.C. §112

In the office action mailed September 8, 2005, the Examiner rejected claims 126, 133, 136 and 137 under 35 U.S.C. §112, first paragraph for alleged lack of written description. Applicants' cancellation of these claims obviates or overcomes this rejection. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Entitlement to Priority

The Examiner asserts that the present application is not entitled to receive the benefits of priority under 35 U.S.C. §§ 120 or 119(e) with respect to the 09/006,352 and 60/035,496 applications because said applications allegedly do not disclose a specific and substantial utility. Thus, the Examiner has accorded the present application an effective filing date of March 4, 1999.

Applicants respectfully disagree.

As stated in M.P.E.P. §2107.02, "an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112...See, e.g., *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) ('When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown.')".

The polypeptide of SEQ ID NO:2 has a specific and substantial utility, for example, in the treatment of graft vs. host disease. This utility is clearly disclosed in the present specification in paragraph [0023] and in the earliest application to which the present application claims priority, namely Application Serial No. 60/035,496 filed January 14, 1997, in the second full paragraph on page 7.

This utility has been confirmed, for example, by Zhang et al., *Journal of Clinical Investigation* 107:1459 (2001), reference CD on the Revised form PTO/SB/08 submitted December 16, 2002, initialed and returned to Applicants with the Office action mailed July 29, 2003), who show that TR6-Fc[2] treatment reduces symptoms in a murine model of graft vs. host disease. The Federal Circuit held in *In re Brana*, evidence dated after the filing date

[2] Full-length human TR6 in Zhang et al. is the same as TNFR6-alpha (SEQ ID NO:2) of the present application.

"can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification." 51 F. 3d. 1560, 1567 at n19 (Fed. Cir. 1995). Such evidence "goes to prove that the disclosure was in fact enabling when filed (*i.e.*, demonstrated utility)." *Id., citing In re Marzocchi*, 439 F2d. at 224 n.4, 169 U.S.P.Q. at 370 n.4.

Applicants emphasize that the asserted utility in the present application is adequate under all applicable authority. Applicants' asserted utility is a specific, substantial and credible utility and not a "throw away" utility (such as using a composition for landfill) as defined in the current United States Patent and Trademark Office's Utility Guidelines.

Because the polypeptide of SEQ ID NO:2 has a specific and substantial utility, the antibodies of the present application also have utility under 35 U.S.C. § 101 because they are useful, for example, to detect or purify a useful protein. Moreover, this utility was clearly set forth in the earliest application to which the present application claims priority, i.e, Application Serial No. 60/035,496 filed January 14, 1997.

Accordingly, Applicants maintain that the present application is entitled to receive the benefits of priority under 35 U.S.C. §§ 120 or 119(e) with respect to the 09/006,352 and 60/035,496 applications and that the present application should be accorded an effective filing date of January 14, 1997.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 49-147 under 35 U.S.C. §102(e), as being anticipated by Ashkenazi et al., U.S. Patent No. 6,764,679 which the Examiner has assigned an effective priority date of September 19, 1998.

As described above, the present application is entitled to a priority date of January 14, 1997 and thus, the Ashkenazi reference, U.S. Patent No. 6,764,679, is not available as prior art under 35 U.S.C. §102 with respect to the present application. Accordingly, Applicants respectfully request that the present rejection be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the Petition for an Extension of Time submitted concurrently herewith, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: October 11, 2005

Respectfully submitted,

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